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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,287	12/08/2000	Steven R. Cohen	MP-00101.P.1.1	2978

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SAN DIEGO, CA 92130

EXAMINER

MANAHAN, TODD E

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 07/18/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/733,287

Applicant(s)

COHEN ET AL.

Examiner

Todd E. Manahan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-25, 38, 42, 52, 55 and 58 is/are pending in the application.
- 4a) Of the above claim(s) 38, 42, 52, 55 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 08 December 2000 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other:

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, drawn to a distraction device and method, classified in class 606, subclass 105.
- II. Claims 38, 42, 52, 55, and 58, drawn to stabilizing device and method, classified in class 606, subclass 60.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II has separate utility such as use with a distraction device that does not comprises biodegradable material. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant's election with traverse of Group I, claims 1-25, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the inventions are "connected by a single, searchable unifying element. This is not found persuasive because the criteria for restriction is that the inventions be independent and distinct. Applicant appears to be confusing U.S. Restriction practice with PCT Unity of Invention practice. Applicant further argues that because the inventions are not independent, restriction is not proper. As set forth in MPEP 802.01 (Edition 8, August, 2001, Latest Revision February 2003 ):

"Independent", of course, means not dependent. If "distinct" means the same thing, then its use in the statute and in the rule is redundant. If "distinct" means something different, then the question arises as to what the difference in meaning between these two words may be. The hearings before the committees of Congress considering the codification of the patent laws indicate that 35 U.S.C. 121: "enacts as law existing practice with respect to division, at the same time introducing a number of changes."

MPEP 802.01 further goes on to define "distinct":

The term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use, or sale as claimed, **AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER** (though they may each be unpatentable because of the prior art). It will be noted that in this definition the term related is used as an alternative for dependent in referring to subjects other than independent subjects.

The criteria for Restriction is set forth in MPEP 803:

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and

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(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).

In the instant application the invention are deemed to be distinct subcombinations useable together and the reasoning to support this has been set forth above. In the first paragraph on page 3 of applicant's response, applicant appears to agree with such distinctness. Applicant however, further contends that there is no serious burden on the examiner because both inventions can be "searched by electronically searching key words". The mere fact that multiple inventions can be search together by keyword searching electronic databases, does not mean there is no serious burden on the examiner. As set forth in MPEP 803:

For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant. Insofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria is set forth in MPEP § 803.02. Insofar as the criteria for restriction or election practice relating to claims to genus-species, see MPEP § 806.04(a) - § 806.04(i) and § 808.01(a).

The examiner has made a prima facie showing of serious burden by showing separate classification and recognized divergent subject matter. Applicant however has not provided sufficient showing or evidence to rebut the examiner's prima facie showing of burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 38, 42, 52, 55, and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

### *Drawings*

The drawings are objected to because figures 1A-1K are photographs. In that the subject matter of applicant's invention admits of illustration by a drawing, these photographs are not in compliance with 37 CFR 1.84 (b)(1). A proposed drawing correction and corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Furthermore, all of the drawing figures should include reference numerals identifying the elements of the invention illustrated therein so as to promote a better understanding of the invention.

The drawings are objected to because figures 1L and 2-5 contain extraneous matter which is not permitted, i.e. dimension lines and dimensions, descriptive wording. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Specification*

The abstract of the disclosure is objected to because it compares the invention with the prior art and also included "means" and "said". Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves

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modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

**The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.**

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The specification is objected to under 37 CFR 1.71 because it fails to provide an adequate written description of the invention.

The application lacks a proper written description of the invention. The detailed description of the invention should employ reference numerals such that each and every part can be identified and described. These reference numerals must also appear in the drawing figures. All parts and their interrelationships must be described to the extent that one skilled in the art could make and use the invention. Appropriate correction is required.

### *Claim Objections*

Claim 18 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 18 recites "said expansion means comprises at least in part a biodegradable, bioerodible or bioresorbable material", however base claim 1 already states "wherein **each of** said first transmitting means, said second transmitting means and said expansion means comprises a biodegradable, bioerodible or bioresorbable material" (emphasis examiner's). as such claim 18 does not place any further limits on the subject matter of base claim 1.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5-6, 10, 11, 13-16, and 22-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite part of the human body in combination with the device, e.g. "said structure...is attached to bone via at least one screw" (claim 5), "said first tissue region comprises connective tissue" (claim 13), "device of claim 1 implanted in a subject" (claim 22), "at least a portion of the activation means is external to the subject" (claim 24). It has been held that a claim directed to or including within its scope, a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of limited, but exclusive property right in a human being is prohibited by the constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970). It is noted that



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applicant's disclosure recites the subject as being "human or non-human", and thus the broadest interpretation thereof, in light of the specification, includes a human.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 19-21, the word "means" is preceded by the word(s) "activation" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no meaningful function is specified by the word(s) preceding "means," i.e. what such 'means' activates, it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-9, 12 and 25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Seldin (U.S. Patent No. 5,672,177 cited by applicant).

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Seldin discloses a implantable distraction device comprising a first transmitting means 12 in the form of a first plate; a second transmitting means 14 in the form of a second plate, and expansion means 44 for exerting a force distracting the first transmitting means from the second transmitting means. The entire device may be formed of biodegradable material (see col. 5, lines 6-10). The expansion means is not integral with the first transmitting means ("wherein said expansion means is not integral with at least one of said first transmitting means or said second transmitting means").

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7-9, 12, 17, 18 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (United States Patent No. 5,364,396 cited by applicant) in view of Seldin.

Robinson discloses the invention essentially as claimed except for "each of said first transmitting means 16, said second transmitting means 18 and said expansion means 20 comprises a biodegradable, bioerodible or bioresorbable material". Seldin discloses that it is known in the art to form an implantable distraction device of biodegradable material "which is designed to break down over time in the body and be absorbed into the surrounding tissues and/or excreted as waste" (col. 5, lines 5-10). It would have been obvious to one skilled in the

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art to form the device of Robinson et al of biodegradable material in view of Seldin in order that the device break down over time in the body and be absorbed into the surrounding tissues and/or excreted as waste.

*Conclusion*

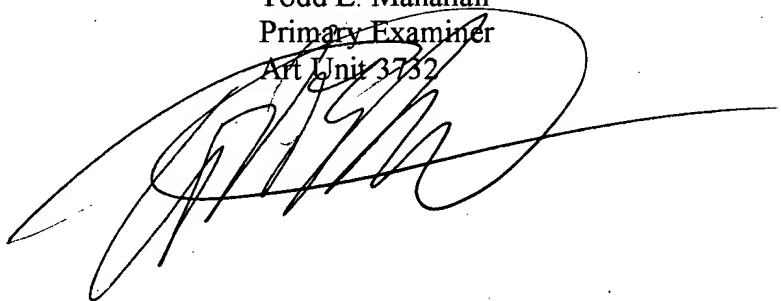
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd E. Manahan whose telephone number is 703 308-2695.

The examiner can normally be reached on Mon-Fri.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

Todd E. Manahan  
Primary Examiner  
Art Unit 3732

T. E. Manahan  
July 17, 2003

A large, stylized handwritten signature in black ink, likely belonging to Todd E. Manahan, is written over the printed name and title.